REMARKS

Claims 1-9, 17-18 and 26-34 are currently under consideration. Claims 26-30 and 32-33 have been amended to so that they further limit the claim from which they depend. Claim 34 has been amended to correct an improper multiple dependency problem. New claims 35 to 37 have been introduced into the claim set. Support is found on page 12, lines 5 to 12 and 19 to 24 of the Specification. No new matter has been added.

1. Rejections under 35 USC §112, second paragraph

The Examiner has rejected claim 29 under 35 USC §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. Specifically, the Examiner states that is in unclear whether the composition contains 2-30% each of germanicol, dammaradienol, 24-methylene-dammarenol and/or parkeol or 2-30% of germanicol. Applicant has amended claim 29 to specify that the composition comprises 2-30% of at least one triterpenes selected from the group consisting of germanicol, dammaradienol, 24-methylene-dammarenol and parkeol. Applicant believes that the amendment has obviated the rejection and, therefore, respectfully requests reconsideration and removal of the rejection.

2. Claim Objections

The Examiner has objected to claims 26-30 and 32-33 under 37 C.F.R. §1.75(c) because the claims did not further limit the claims from which they depend. Applicant has amended the preamble of these claims so that it is now clear that these claims further limit the pharmaceutical composition or dietary supplement according to claim 1, 2 or 3. The Examiner has also objected to claim 34 as being in improper multiple dependent form. Applicant has amended the claim to correct the improper multiple dependency. Reconsideration and removal of the objection is respectfully requested.

3. Rejections under 35 USC §103(a)

A. Laur et al. (US 5,679,393)

The Examiner has maintained the rejection of claims 1-5, and 7-9 under 35 U.S.C. § 103(a)as being unpatentable over Laur et al, US 5,679,393. Applicant had previously argued that the Laur et al. mixture did not disclose or suggest the compositions of the present invention. Specifically, Applicant asserted that Laur et al. does not teach the skilled person to provide compositions comprising at least 0.1% of each of the triterpenes, α-amyrin, β-amyrin, butyrospermol and lupeol for achieving the anti-inflammatory effect of the present invention. In response, the Examiner states that the unsaponifiable material of Laur et al. inherently contains the recited components lupeol, sigmasterol, amyrin and butyrospermol (parkeol). The Examiner goes on to state that it is the Applicant's duty to demonstrate that the prior art compositions do not possess these inherent features. Applicant respectfully traverses.

Applicant has amended claim 1 to recite that the composition comprises fron 5-90% by weight of the lupeol and/or the butyrospermol. Support for this limitation may be found on page 12, lines 5 to 11 and 19 to 24, of the Specification. Applicant submits that the Laur *et al.* reference does not disclose or suggest producing compositions comprising lupeol and/or butyrospermol in a weight percentage ranging from between 5-90%.

As previously noted, the Laur *et al.* reference discloses compositions comprising a mixture of fractions rich in unsaponifiable materials obtained according to a particular process (*see, for example*, claim 14 and col. 5, lines 30-44). Such unsaponifiable materials are obtained by a process including mixing a first fraction of unsaponifiable materials insoluble in hot ketone solvent together with a second fraction of unsaponifiable materials soluble in hot ketone solvent, wherein the latter fraction is isolated by crystallization. As can be derived from example 1 of the Laur *et al.* reference, the insoluble first fraction represents strongly apolar unsaponifiable constituents of the gum or latex type containing the karitene (col. 8, lines 55 to 59). The reference also states that the mixtures of enriched fractions of unsaponifiable materials contain all the native constituents in Shea Butter such as karitenes, triterpenic alcohols and sterols (col. 12, lines 40 to 45).

In light of these teachings, a person of ordinary skill in the art would interpret the Laur *et al.* reference as teaching a process for producing fractions rich in unsaponifiable materials containing all the native constituents in Shea butter (karitenes, triterpenic alcohols and sterols). Such an interpretation is also supported by referring to Examples 7, 8, 9 and 10, in the Laur et al. reference. The compositions comprise between 1-60%, 2-10%, 10-25% and 10-20% of an extract of unsaponifiable material. More preferably, the content of an extract of unsaponifiable material in the compositions is 5% or 15% (see Examples 7-10). According to the extraction procedure used by Laur et al, the extract contains between 18 to 50% of unsaponifiable matter (see, for example, claim 15). Thus, as may be understood, the Laur et al. reference describes compositions comprising between 1-60% of an extract of unsaponifiable matter, which at a maximum contains 50% of unsaponifiable material. Thus, Laur et al. suggest compositions maximally comprising 30% of unsaponifiable material (50*60/100).

The Examiner may note that the Laur et al. reference suggests using extracts of unsaponifiable matter, wherein the karitenes are also present in enriched levels (see Example 5) although such type of compounds may be disadvantageous in pharmaceutical compositions due to their very insoluble character and gummy nature. However, given the fact that the Laur et al. compositions are used as cosmetic and pharmaceutical compositions, Applicant submits that it is reasonable to assume that the Laur et al. compositions may only contain a limited amount of such such karitene-enriched extracts. Accordingly, Applicant submits that Laur et al. only exemplifies compositions comprising up to 60% of unsaponifiable material and preferably less, such as 5% or 15%.

A person of ordinary skill in the art would be able to estimate the content of individual terpenes in Shea Butter using data from publicly available sources. As can be seen from the table below, the relative content of triterpenes in the unsaponifiable material of Shea Butter ranges from 65 to 75% and the relative content of karitenes ranges between 18 and 30%. Thus, on average about 70% of the unsaponifiable material of Shea Butter consists of triterpenes and the remaining 25% of the unsaponifiable material consists of karitenes. Given that the compositions of Laur et al. maximally contain 30% of unsaponifiable material, the content of triterpenes may be estimated to be about 21% ($\frac{30*70}{100}$) and that of karitenes to be about 8%.

Class of compounds in Shea Butter	Content (% w/w)		
	min	max	Mean
Triterpenes	65	75	70
Sterols	3	7	5
Karitenes	18	30	25

The relative content (average) of the triterpenes, Butyrospermol, sum of α-Amyrin and β-Amyrin and Lupeol, in the triterpenic fraction can also be derived from the literature:

Butyrospermol: 21%.
α-Amyrin and β-Amyrin: 51%.
Lupeol: 18%.

The literature data derives from:

1) Itoh: Oléagineux (1974), 29(5), p. 253 - 258
2) Peers: J. Sci. Food and Agriculture (1977), 28, p. 1000 - 1009
3) Itoh: Lipids (1980), 15(6), p. 407 - 411
4) Paquot: Oléagineux (1952), 7(7), p. 397 - 402

Given that an extract of unsaponifiable material obtained according to the method of Laur et al comprises each of the triterpenes in relative amounts corresponding to that of native Shea butter, the average content of individual triterpenes in a composition according to Laur et al can be estimated. With respect to a composition comprising on an average basis about 21% of a triterpenic fraction comprising 21% of butyrospermol, the content of butyrospermol would be about 4.4%.

Content of individual triterpenes in a composition according to Laur et al:

Butyrospermol: 4.4 %.
α-Amyrin and/or β-Amyrin: 10.6%.
Lupeol: 3.9 %.

Thus, a composition of Laur that comprises 60% of an extract comprising 50% of unsaponifiable material would inherently contain about 21% of a triterpenic fraction. And, consequently, such compositions would inherently contain about 4.4% of butyrospermol, 3.9 % of Lupeol and 10.6 % of α-Amyrin and β-Amyrin.

The foregoing remarks demonstrate that the skilled artisan, in possession of the literature data cited above and the Laur et al. reference, would not believe that the Laur et al. compositions inherently contain the claimed levels of the individual triterpenes in the instant application. Moreover, it should also be emphasized that Laur et al does not describe or suggest using the levels of the individual triterpenes in a pharmaceutical composition as disclosed in the present invention. Accordingly, Applicant submits that the instant claims are novel and non-obviousness over the Laur et al. reference. Reconsideration and removal of the rejection is respectfully requested.

B. Laur et al. and SU 1181171

The Examiner has rejected claim 6 in view of the combined teachings of Laur et al. and SU 1181171. The Examiner argues that it would be obvious to combine the extract of *Calendula officinalis* with the Laur et al. composition which is described as containing shea butter extracts which the same levels of triterpenes and sterols as the instant composition. Applicant respectfully traverses.

The foregoing remarks demonstrate that the compositions according to amended claim 1 are patentably distinguishable from Laur et al. Accordingly, Applicants submit that claim 6 is also patentably distinguishable over the combined teachings of Laur et al. and SU 1181171. Reconsideration and removal of the rejection is respectfully requested.

C. Laur et al. and WO 99/22706

Finally, the Examiner has maintained the rejection of claims 17 and 18 in view of the combined teachings of Laur et al. and WO 99/22706. WO 99/22706 is cited for disclosing compositions comprising extracts of *B. parkii* for use as dermatological, anti-inflammatory and vulnerary compounds. The Examiner argues that a person of ordinary skill in the art would be motivated to combine the teachings of Laur et al. with WO 99.22706 to arrive at the instant invention. Applicant respectfully disagree. WO 99/22706 describes compositions comprising extracts from the flower of *B. parkii*, whereas the Laur et al. compositions use extracts from the fruit of *B. parkii*. It is doubtful that a person of ordinary skill in the art would be motivated to combine the teachings of these two references as the extracts are derived from different plant parts

and are known to possess different properties. Accordingly, Applicant submits that the Examiner has not established a *prima facie* case of obviousness as there is no motivation or suggestion within the references which suggest that the extracts from fruits and interchangeable with the extracts from the flower. Reconsideration and removal of the rejection is respectfully requested.

The above comments will be further supported by a Declaration under Rule 132 that will be submitted shortly, supplemental to the response.

Favorable action and the early allowance of the claims are requested.

Pursuant to 37 C.F.R. §§ 1.17 and 1.136(a), the Applicant respectfully petitions for a three (3) month extension of time for filing a response in connection with the present application and the required fee of $ 465.00 is attached hereto.

The Commissioner is hereby authorized to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17; particularly, extension of time fees.

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(Date of Deposit)

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Respectfully submitted,

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Attachments: Marked Up Version of the Claims to Show Changes Made

Amended Claim Set

1. (Twice amended). A pharmaceutical composition or a dietary supplements comprising ~~an extract or concentrate of Butyrospermum parkii comprising~~ at least 5% (w/w) of a ~~Butyrospermum~~ triterpene fraction obtained from Butyrospermum parkii~~such that said composition comprises at least 5 % w/w of said Butyrospermum triterpene fraction~~ comprising~~,~~

~~said Butyrospermum triterpene fraction comprises~~:

- at least 2% (w/w) lupeol;
- at least 2% (w/w) α-amyrin and/or β-amyrin; and
- at least 2% (w/w) butyrospermol;

wherein said triterpenes, lupeol, α-amyrin, β-amyrin and/or butyrospermol, may be in the form of free alcohols or esters thereof;

and wherein ~~,~~

said lupeol or said butyrospermol is in a weight percentage in the composition ranging from 5-90%.

2. (Twice amended). The pharmaceutical composition or a dietary supplement according to claim 1, wherein said ~~Butyrospermum~~ triterpene fraction comprises:

- 10-40% (w/w) lupeol;
- 10-40% (w/w) α-amyrin and/or β-amyrin; and
- 10-40% (w/w) butyrospermol~~;~~,

wherein said triterpenes, lupeol, α-amyrin, β-amyrin and/or butyrospermol, may be in the form of free alcohols or esters thereof;

3. (Twice amended). The pharmaceutical composition or dietary supplement according to claim 1, ~~wherein the extract or concentrate of Butyrospermum parkii~~ further comprisinges a sterol fraction comprising at least one sterol selected from the group consisting of stigmasterol, avanasterol, 24-methyl-cholest-7-enol, karitesterol A, karitesterol B and α-spinasterol, wherein said sterols may be in the form of free alcohols or esters thereof.

4. (Twice amended). The pharmaceutical composition or dietary supplement according to claim 1, wherein the ~~Butyrospermum~~ triterpene fraction is in a weight percentage ~~comprises~~ of at most ~~up to~~ 100% (w/w) ~~of the extract or concentrate of Butyrospermum parkii~~.

5. (Twice amended). The pharmaceutical composition or dietary supplement according to claim 3, wherein the ratio between the ~~Butyrospermum~~ triterpene fraction and the sterol fraction is in the range of 1:100 to 500:1 (w/w).

6. (Previously amended). The pharmaceutical composition or dietary supplement according to claim 1, further comprising an extract of Calendula officinalis.

7. (Previously amended). The pharmaceutical composition according to claim 1 formulated for systemic administration.

8. (Previously Amended). The pharmaceutical composition according to claim 1 formulated for topical administration.

9. (Previously Amended). The pharmaceutical composition according to claim 8, wherein the pharmaceutical composition is formulated as a fluid, ointment, gel, liniment, emulsion or spray (e.g. aerosol).

17. (Twice amended). A method for treating hypersensitivity or inflammation in a mammal, characterised by administering ~~a composition comprising an extract or concentrate of Butyrospermum parkii comprising~~ at least 5% (w/w) of a ~~Butyrospermum~~ triterpene fraction obtained from Butyrospermum parkii ~~such that said composition comprises at least 5 % w/w of said Butyrospermum triterpene fraction, said Butyrospermum triterpene fraction~~ comprisinges:

- at least 2% (w/w) lupeol;
- at least 2% (w/w) α-amyrin and/or β-amyrin; and
- at least 2% (w/w) butyrospermol;

wherein said triterpenes, lupeol, α-amyrin, β-amyrin and/or butyrospermol, may be in the form of free alcohols or esters thereof.

18. (Previously amended). The method according to claim 17, wherein the treating of hypersensitivity or inflammation is for the treating of hypersensitivity of the skin or mucous membranes of a mammal.

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26. (Currently amended). The pharmaceutical composition or dietary supplement according to claim ~~The method according to claim~~ 1, further comprising a pharmaceutically acceptable carrier.

27. (Currently amended). The pharmaceutical composition or dietary supplement according to claim~~The method according to claim~~ 1, further comprising at least 1% germanicol, dammaradienol, 24-methylene-dammarenol and/or parkeol,

28. (Currently amended). The pharmaceutical composition or dietary supplement according to claim~~). The method according to claim~~ 1, wherein said esters are selected from the group consisiting of cinnamic acid esters, acetic acid esters and fatty acid esters.

29. (Currently amended). The pharmaceutical composition or dietary supplement according to claim ~~The method according to claim~~ 2, further comprising 2-30% of at least one triterpenes selected from the group consisting of germanicol, dammaradienol, 24-methylene-dammarenol ~~and~~/or parkeol,

30. (Currently amended). The pharmaceutical composition or dietary supplement according to claim ~~The method according to claim~~ 3, wherein said esters are selected from the group consisting of cinnamic acid esters, acetic acid esters and fatty acid esters.

31. (Currently amended). The pharmaceutical composition or dietary supplement according to claim 3, wherein the ~~Butyrospermum~~ triterpene fraction together with the ~~and the~~ sterol fraction is in a weight percentage of at most ~~comprises up to~~ 100% (w/w) ~~of the extract or concentrate of Butyrospermum parkii.~~.

32. (Currently amended). The pharmaceutical composition or dietary supplement according to claim ~~The method according to claim~~ 1, wherein the triterpene fraction ~~extract or concentrate of Butyrospermum parkii~~ is derived from the fruit, leaves, stem, bark or root of Butyrospermum parkii.

33. (Currently amended). The pharmaceutical composition or dietary supplement according to claim ~~The method according to claim~~ 32, wherein the triterpene fraction ~~extract or concentrate of Butyrospermum parkii~~ is derived from the fruit of Butyrospermum parkii.

Currently Amended

34. (~~New~~). The method according to claim 17, wherein said triterpene fraction is in a composition ~~is~~ as defined in any one of claims 1~~2 to 9, 26 to 33~~.

35. (New). The pharmaceutical composition or dietary supplement according to claim 1, wherein said butyrospermol is in a weight percentage in the composition ranging from 8-40%.

36. (New). The pharmaceutical composition or dietary supplement according to claim 1, wherein said butyrospermol is in a weight percentage in the composition ranging from 9-40%.

37. (New). The pharmaceutical composition or dietary supplement according to claim 1, wherein said lupeol is in a weight percentage in the composition ranging from 7-40%.

38. (New). The pharmaceutical composition or dietary supplement according to claim 1, wherein said lupeol is in a weight percentage in the composition ranging from 8-40%.